



125

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,839	07/14/2003	J. David Lambeth	05501-0211 (43150-286808)	8208
23370	7590	06/01/2004	EXAMINER ALONZO, NORMA LYN	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET SUITE 2800 ATLANTA, GA 30309			ART UNIT 1632	PAPER NUMBER
DATE MAILED: 06/01/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/618,839	LAMBETH ET AL.
	<b>Examiner</b> Norma C Alonzo	<b>Art Unit</b> 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) 1-26 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_.

**DETAILED ACTION**

1. Claims 1-26 are pending.

***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6, 9-17, and 26, drawn to a transgenic non-human animal comprising the sequence of SEQ ID NO: 1, a cell or cell line derived from said transgenic non-human animal, and a method of using said transgenic non-human animal, classified in class 800, subclass 8.
  - II. Claims 1-5, 9-17, and 26, drawn to a transgenic non-human animal comprising the sequence of SEQ ID NO: 3, a cell or cell line derived from said transgenic non-human animal, and a method of using said transgenic non-human animal, classified in class 800, subclass 8.
  - III. Claims 1-5, 9-17, and 26, drawn to a transgenic non-human animal comprising the sequence of SEQ ID NO: 5, a cell or cell line derived from said transgenic non-human animal, and a method of using said transgenic non-human animal, classified in class 800, subclass 8.

- IV. Claims 1-5, 9-17, and 26, drawn to a transgenic non-human animal comprising the sequence of SEQ ID NO: 7, a cell or cell line derived from said transgenic non-human animal, and a method of using said transgenic non-human animal, classified in class 800, subclass 8.
- V. Claims 1-5, 9-17, and 26, drawn to a transgenic non-human animal comprising the sequence of SEQ ID NO: 9, a cell or cell line derived from said transgenic non-human animal, and a method of using said transgenic non-human animal, classified in class 800, subclass 8.
- VI. Claims 1-5, 9-17, and 26, drawn to a transgenic non-human animal comprising the sequence of SEQ ID NO: 11, a cell or cell line derived from said transgenic non-human animal, and a method of using said transgenic non-human animal, classified in class 800, subclass 8.
- VII. Claims 1-5, 9-17, and 26, drawn to a transgenic non-human animal comprising the sequence of SEQ ID NO: 13, a cell or cell line derived from said transgenic non-human animal, and a method of using said transgenic non-human animal, classified in class 800, subclass 8.
- VIII. Claims 7-8 and 19-20, drawn a transgenic non-human animal comprising a transgene encoding a NADPH oxidase enzyme or dual oxidase enzyme

and further comprising a nonsense mutation in a murine adenomatous polyposis coli gene, and a method for using said transgenic non-human animal, classified in class 800, subclass 8.

- IX. Claims 21-25, drawn a vector comprising a transgene wherein the transgene is SEQ ID NO: 1 and a cell containing the said vector, classified in class 435, subclass 325.
- X. Claims 21-25, drawn to a vector comprising a transgene wherein the transgene is SEQ ID NO: 3 and a cell containing the said vector, classified in class 435, subclass 325.
- XI. Claims 21-25, drawn to a vector comprising a transgene wherein the transgene is SEQ ID NO: 5 and a cell containing the said vector, classified in class 435, subclass 325.
- XII. Claims 21-25, drawn to a vector comprising a transgene wherein the transgene is SEQ ID NO: 7 and a cell containing the said vector, classified in class 435, subclass 325.

XIII. Claims 21-25, drawn to a vector comprising a transgene wherein the transgene is SEQ ID NO: 9 and a cell containing the said vector, classified in class 435, subclass 325.

XIV. Claims 21-25, drawn to a vector comprising a transgene wherein the transgene is SEQ ID NO: 11 and a cell containing the said vector, classified in class 435, subclass 325.

XV. Claims 21-25, drawn to a vector comprising a transgene wherein the transgene is SEQ ID NO: 13 and a cell containing the said vector, classified in class 435, subclass 325.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I-VIII are drawn to transgenic non-human animals comprising transgenes encoding different sequence compositions, cells or cell lines derived from said transgenic non-human animals, and methods of using said transgenic non-human animals. The inventions of groups I-VIII are drawn to compositions and methods comprising compositions that are distinct and described in the specification as “unique proteins.” The transgenic non-human animals of groups I-V comprising transgenes that encode homologs of proteins belong to the family of nicotinamide adenine dinucleotide phosphate-reduced form (NADPH) oxidase (NOX), while the transgenic non-human animals of groups VI-VII comprise transgenes that encode

members from the family of dual oxidase enzymes (DOX). While expressing the proteins of the same transgene family, animals of various groups (I-VII) are patentably distinct each from the other because such animals would have different phenotypes and utilities due to the expression of proteins that have distinct and different biological functions. For example, while NOX1 (SEQ ID NO: 1) and NOX4 (SEQ ID NO: 8) belong to the same enzyme family, NOX 1 co-localizes in caveolae-like structures with caveolin1, whereas NOX 4 co-localizes with vinculin in focal adhesions. Additionally, while NOX1 (SEQ ID NO: 1) and Duox1 (SEQ ID NO: 12) both belong to the gp91*phox* homologue family, the NOX enzymes have signaling roles, whereas Duox enzymes are implicated in biosynthetic reactions that involve extracellular matrix proteins. Therefore, the inventions are different, each from the other and are patentably distinct.

3. The inventions of groups IX-XV are drawn to a vector comprising transgenes encoding different sequence compositions and described in the specification as "unique proteins." The vectors of groups IX-XIII comprise a transgene encoding homologs of proteins from the family of nicotinamide adenine dinucleotide phosphate-reduced form (NADPH) oxidase (NOX), while the invention of groups XIV-XV encode members from the family of dual oxidase enzymes (DOX). While derived from the same homologue family, they are patentably distinct each from the other because they would have different modes of operation, different functions, or different effects since the function of these proteins, especially their homologs, are not clear. Proteins encoded by homologous transgenes do not necessarily exhibit identical structures, functions or

Art Unit: 1632

effects. For example, the vector comprising the homolog of NOX1 as encoded by SEQ ID NO: 1 would encode an enzyme that catalyzes the reduction of NADOH. On the other hand, a vector comprising the homolog of DOX1 as encoded by SEQ ID NO: 11 would encode an enzyme that catalyzes the reduction of dual oxidases. Therefore, the inventions of groups IX-XV are different, each from the other and are patentably distinct.

4. The inventions of groups I-VIII, transgenic non-human animals, are patentably distinct from the inventions of groups IX-XV, vectors comprising transgenes, because animals have structure, function and utilities that are not shared by any of the groups IX-XV. While the vector can be used for making the non-human transgenic animals, they can also be used to generate a cell line or a fusion protein and the transgenic non-human animal can be generated from something other than a vector such as a linearized plasmid as done in generation of transgenic amphibians.

5. Claims 10 and 23 are generic to a plurality of disclosed patentably distinct species comprising the tissue-specific promoters CX1, SV40 early promoter, cytomegalovirus promoter, mouse mammary tumor virus steroid-inducible promoter, or Moloney murine leukemia virus. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

Art Unit: 1632

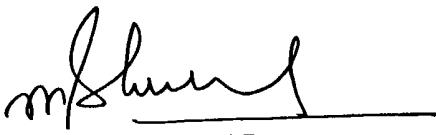
case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Norma C Alonzo whose telephone number is 571-272-2910. The examiner can normally be reached on 8-5pm.



RAM R. SHUKLA, PH.D.  
PRIMARY EXAMINER